

REMARKS

The present invention relates to a skull pin including a removable tip. The tip is formed from an insulating material, preferably a ceramic. Claims 1-4, 6-8, 11, 12 and 14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 4,612,930 to Bremer in view of United States Patent No. 6,387,129 to Rieser, et al. The Examiner further notes in the Advisory Action dated 5/15/03, that United States Patent No. 5,042,462 to Bremer discloses a rounded tip in FIG. 4. The claims of the present application have been amended, and Applicant contends this rejection has thereby been obviated.

The independent claims of the present application have been amended to recite that the rounded tip of the pin has a radius in the range of 0.025 to 0.075 mm. Neither Rieser nor Bremer disclose a rounded tip with a radius in this range. The significance and inventiveness of Applicant's rounded tip and radius range will now be described.

Rieser shows a tip that is rounded, but not in the range claimed by Applicant. Additionally, Rieser's rounded tip is on a threaded screw whereas Applicant's is on a screw with straight sides. Accordingly, the radius of Rieser's rounded tip is not significant because it does not bear on the ability of the screw to penetrate material, the way is necessary with Applicant's smooth-sided pin. Applicant's smooth-sided pin must have a tip with a radius small enough to allow the pin to penetrate bone and remain in it, but large enough so the pin tip has sufficient strength and will not break during use. Therefore, for the pin type claimed by Applicant, determination of the optimum pin tip radius required inventive reasoning and conclusions. (See Declaration of Lisa A.G.

Twearthy, attached.) Applicant has determined and claimed the ideal radius (p.7, lines 15-22). Nowhere does Rieser address pin tip radius, even though Rieser addresses other screw dimensions (col. 4, line 62 through col. 5, line 7). Clearly Rieser has not disclosed the significance of a particular pin tip radius range. Even if Rieser's tip is rounded, it is not in the range of Applicant's claimed radius.

Bremer also does not recognize, disclose or suggest the significance of a rounded pin tip having a radius in the range of 0.025-0.075 mm in either the '930 or '462 patent. Even though Bremer recognizes the brittleness of insulating materials (col. 1, lines 57-61), Bremer does not address Applicant's solution of using a rounded tip having a radius in the range of 0.025-0.075 mm. Bremer's '930 patent shows only a pointed pin tip. Bremer's '462 patent also shows only a pointed tip. Although the Examiner states that the '462 patent shows a rounded tip in FIG.4, the patent states that it is a pointed tip. FIG. 4 is described as "a perspective exploded view of an exemplary pin, and a *pointed* pin tip...". (emphasis added) In fact, the tip (part 26) is described as pointed throughout the patent. The Scribner-Bantam English Dictionary defines "pointed" as, "sharp". Applicant's claimed radius would not render the pin tip "sharp".

Independent Claims 1, 7 and 9, which include a pointed tip having a radius in the range of 0.025 to 0.075 mm, are patentable over Bremer or Rieser, and so too are claims 2-6, 8 and 10-15, which depend thereon.

The Examiner has provided that Bremer's '930 FIG. 3 shows a tip having a tapered portion in the range of 30° -50°. Applicant respectfully invites the Examiner's attention again to FIG. 4 as provided in Exhibit A of this response. Applicant has drawn on

Bremer's FIG. 4 the angle in question. As can be seen upon measurement from the drawing, Bremer's angle is 56°, and clearly not in Applicant's claimed range. Applicant has added new claim 16 that includes the tapered portion having an angle in the range of 30° -50°. This angle is clearly not disclosed by Rieser or Bremer and, therefore, Claim 16 is patentable over both.

Applicant notes that the amendment made to the specification was done to change the term "pointed" to "rounded end" which was the original terminology in the patent. The term had been mistakenly changed in the last amendment when Applicant was addressing the 112 rejection regarding an incorrect part number.

Accordingly, Applicant believes that the invention as set forth in the amended claims is patentable over the cited prior art, and respectfully requests early and favorable notification to that effect.

Respectfully submitted,
SCHNADER HARRISON SEGAL & LEWIS LLP

Dated: July 15, 2003 By: Joan T. Kluger
JOAN T. KLUGER
Registration No. 38,940
1600 Market Street, Suite 3600
Philadelphia, PA 19103
Direct Dial: (215) 751-2357
Facsimile: (215) 751-2205
E-Mail: jkluger@schnader.com
Attorneys for Applicant

In the Specification

Version with Markings to Show Changes to the Specification

Please replace the last paragraph on page 7 with the following:

The angle 36 between the tapered portions 26 is about 40° but can be in the range of about 30° to 50° . The angle must be chosen so that the angle is sufficiently small to be capable of holding the pin in place in the bone of the patient's skull, while not so small that the pin will break easily. The radius of ~~point~~ rounded end 28 is between 0.025 and 0.075 mm, preferably between 0.04 and 0.06, and more preferably about 0.05 mm. The radius is chosen so that pin tip 14 does not slip out of the patient's bone, but yet the tip is structurally strong and stable. The radius can be made larger or smaller than 0.05 mm, providing it meets these conditions.

In the Claims

1. (Twice Amended) A skull pin comprising:

 a pin body; and

 a pin tip formed from an insulating material, protruding from a proximal end of said pin body; wherein the protruding portion of said pin tip consists of a straight-sided portion and a tapered portion with a rounded tip having a radius in the range of 0.025 to 0.075 mm.
2. The skull pin of claim 1, wherein said insulating material is a ceramic material.
3. The skull pin of claim 1, wherein said insulating material is an electrical insulator.

4. The skull pin of claim 1, wherein said pin body includes a bore for receiving said pin tip.
5. The skull pin of claim 1, wherein said pin tip includes a bore for receiving said pin body.
6. (Amended) The skull pin of claim 1, wherein the tapered portion has an angle between 30° and 50°.
7. (Amended) A kit comprising:
 - a halo; and
 - a skull pin, wherein said skull pin comprises
 - a pin body, and
 - an insert formed from an insulating material, protruding from a distal end of said pin body wherein the protruding portion of said insert consists of a straight-sided portion and a tapered portion with a rounded tip having a radius in the range of 0.025 to 0.075 mm.
8. The kit of claim 7 wherein said insulating material is a ceramic.
9. (Twice Amended) A kit comprising:
 - skull tongs; and
 - a skull pin, wherein said skull pin comprises
 - a pin body, and
 - an insert formed from an insulating material, protruding from a distal end of said pin body wherein the protruding portion of said insert consists of a straight-sided

portion and a tapered portion with a rounded tip having a radius in the range of 0.025 to 0.075 mm.

10. The kit of claim 9 wherein said insulating material is a ceramic.
11. ~~(New)~~ The pin of claim 1 wherein said straight-sided portion is cylindrical.
12. ~~(New)~~ The kit of claim 7 wherein said straight-sided portion is cylindrical.
13. ~~(New)~~ The kit of claim 9 wherein said straight-sided portion is cylindrical.
14. ~~(New)~~ The kit of claim 7 wherein the tapered portion has an angle between 30° and 50°.
15. ~~(New)~~ The kit of claim 9 wherein the tapered portion has an angle between 30° and 50°.
16. (New) A skull pin comprising:

a pin body; and

a pin tip formed from an insulating material, protruding from a proximal end of said pin body;

wherein the protruding portion of said pin tip consists of a straight-sided portion and a tapered portion with a rounded tip; and

wherein the tapered portion has an angle between 30° and 50°.